

animals, the test must have a specificity comparable to the specificity of the currently approved tests. For a test to be approved as a live animal screening test for the identification of suspect animals, the test must be usually reliable but need not be definitive for diagnosing scrapie.

(d) Specific guidelines for use of approved scrapie tests within the Scrapie Eradication Program or Scrapie Flock Certification Program will be added to this part as tests are approved and will also be contained in the Scrapie Eradication UM&R and the Scrapie Flock Certification Program standards based on the characteristics of the test, including specificity, sensitivity, and predictive value.

(e) If an owner elects to have an unofficial test conducted on an animal for scrapie, or for the proteinase resistant protein associated with scrapie, and that animal tests positive to such a test, the animal will be designated a suspect animal, unless:

(1) The test was run as part of a bona fide research protocol designed to evaluate an unapproved test in which the owner is not informed of the test result; or

(2) The test protocol includes appropriate measures to prevent the spread of scrapie.

**§ 54.11 Approval of laboratories to run official scrapie tests and official genotype tests.**

(a) State, Federal, and university laboratories, or in the case of genotype tests, private laboratories will be approved by the Administrator when he or she determines that the laboratory:

(1) Employs personnel assigned to supervise the testing who are qualified to conduct the test based on education, training, and experience and who have been trained by the National Veterinary Services Laboratories (NVSL) or who have completed equivalent training approved by NVSL;

(2) Has adequate facilities and equipment to conduct the test;

(3) Follows standard test protocols;

(4) Meets check test proficiency requirements;

(5) Meets recordkeeping requirements;

(6) Will retain records, slides, blocks, and other specimens from all cases for at least 1 year and from positive cases for 5 years;

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours; and

(8) Will report all test results to State and Federal animal health officials within agreed timeframes. An inspection may include, but is not limited to, review and copying of records, examination of slides, observation of the test being conducted, and interviewing of personnel.

(b) A laboratory may request approval to conduct one or more types of scrapie test or genotype test on one or more types of tissue. To be approved, a laboratory must meet the requirements in paragraph (a) of this section for each type of test and for each type of tissue for which they request approval.

(c) The Administrator may withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (a) of this section. The Administrator shall give written notice of the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing will be held to resolve the conflicts.

**Subpart B—Scrapie Flock Certification Program**

**§ 54.20 Administration.**

The Scrapie Flock Certification Program is a cooperative effort between APHIS; members of the sheep and goat industry, including owners of flocks, slaughtering and rendering establishments, and breed associations and registries; accredited veterinarians; and State governments. APHIS coordinates with State scrapie certification boards and State animal health agencies to encourage flock owners to certify their flocks as free of scrapie by being in continuous compliance with the Scrapie Flock Certification Program standards.